106TH CONGRESS
1ST SESSION

H. R. 2927

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1999

Mr. BROWN of Ohio (for himself, Mr. BERRY, Mr. STARK, Mr. ALLEN, Ms. SCHAKOWSKY, Mr. SANDERS, Mr. KUCINICH, Mr. STRICKLAND, Mr. BARRETT of Wisconsin, and Mr. WYNN) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Affordable Prescription Drugs Act".

SEC. 2. COMPULSORY LICENSING OF CERTAIN PATENTED MEDICAL INVENTIONS.

(a) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"§ 158. Compulsory licensing

"(a) COMPULSORY LICENSING OF CERTAIN PATENTED MEDICAL INVENTIONS.—In the case of any subject invention relating to health in which a patent holder, contractor, exclusive licensee, or assignee has acquired title under this title, the Secretary of Health and Human Services shall have the right to establish other use of the subject matter of the patent without authorization of the right holder if the Secretary makes the determination described in subsection (b).

"(b) DETERMINATION.—The determination of the Secretary of Health and Human Services referred to in subsection (a) is a determination that—

"(1) the patent holder, contractor, licensee, or assignee referred to in subsection (a) has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in a field of use;

"(2) such compulsory license is necessary to alleviate health or safety needs which are not ade-

quately satisfied by the patent holder, contractor, licensee, or assignee; or

"(3) the patented material is priced higher than may be reasonably expected based on criteria developed by the Secretary of Commerce.

"(c) FACTORS IN AUTHORIZING OTHER USE.—In exercising the right under subsection (a) to authorize other use of the subject matter of a patent, the following shall apply:

"(1) Authorization of such use shall be considered on its individual merits.

"(2) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public noncommercial use, where the Government or (if applicable) a contractor of the Government,

without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the Government, the right holder shall be informed promptly.

"(3) Such use shall be nonexclusive.

"(4) Such use shall be nonassignable, except with that part of the enterprise or goodwill which enjoys such use.

"(5) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon appropriate request, the continued existence of such circumstances.

"(6) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

"(7) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct Federal authority.

"(8) Any decision relating to the remuneration provided in respect of such use shall be subject to

judicial review or other independent review by a distinct Federal authority.

"(9) The condition set forth in paragraph (2) is not applicable where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. The competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

"(10) Where such use is authorized to permit the exploitation of a patent ('the 2nd patent') which cannot be exploited without infringing another patent ('the 1st patent'), the following additional conditions shall apply:

"(A) The invention claimed in the 2nd patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the 1st patent.

"(B) The owner of the 1st patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the 2nd patent.

"(C) The use authorized in respect of the 1st patent shall be nonassignable except with the assignment of the 2nd patent.

"(d) CONSISTENCY WITH TRIPS.—Regulations adopted under subsection (a) shall be consistent with provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act.".

(b) CONFORMING AMENDMENT.—the table of contents for chapter 14 of title 35, United States Code, is amended by adding at the end the following new item:

"158. Compulsory licensing.".

SEC. 3. REPORT ON PHARMACEUTICAL COSTS AND SALES.

(a) REPORT REQUIREMENT.—Any person engaged in the manufacture and sale of any drug approved under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) for which a patent is still in effect shall report to the Congress annually an audit of all financial information relevant to the pricing of that drug nationally and internationally, including the costs of research and development, sufficient to assess the reasonableness of that pricing, in accordance with specifications developed by the Secretary of Commerce in consultation with the Commissioner of Food and Drugs.

(b) DISQUALIFICATION FROM PARTICIPATION IN FEDERAL PROGRAMS AS PENALTY FOR NONCOMPLI-

ANCE.—In the case of a person who the Secretary of Commerce determines has failed to submit a report required under subsection (a) on a timely basis, the person shall be ineligible to receive payment from the Federal Government or under any Federal program (including under the medicare and medicaid programs) for any prescription drug or biologic it manufactures or sells until the date the Secretary determines that such failure has ceased.

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